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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,939	03/16/2001	Mary Capelli-Schellpfeffer	3066.1000-001	7242

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EXAMINER	
GHALI, ISIS A D	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/810,939	CAPELLI-SCHELLPFEFFER, MARY	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/12/2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *80,89,103,109 and 111-118* is/are pending in the application.

4a) Of the above claim(s) *112-118* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *80,89,103,109 and 111* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicant's amendment filed 10/12/2006.

Claims 1-79, 81-88, 90-102, 104-108, and 110 have been cancelled.

Claims 80, 89, 103, 109 and 111-118 are pending.

Election/Restrictions

1. This application contains claims 112-118 drawn to an invention nonelected in the response filed 02/23/2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 80, 89, 103, 109, and 111 are included in the prosecution.

The following rejections has been overcome by virtue of applicant's remarks:

Rejection of claims 80, 89, 103, 109 and 111 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The following rejections have been discussed in the previous office action, and are maintained for reasons of record:

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 80, 89, 103, 109, and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 08-259465 ('465).

JP '465 teaches external preparation containing NSAID including indomethacin and flufenamic acid, carrier including gel (instantly claimed in claims 89 and 109 as thermal insulating material) and polyethylene glycol (abstract; paragraphs 0008, 0019). The reference teaches that the external preparation is useful to treat skin diseases such as keloid and hypertrophic scar and does not have adverse effects (paragraph 0022). The NSAID is present in the preparation in an amount of 1-60% (abstract).

JP '465 suggests the treatment of keloid and hypertrophic scar using NSAID, however, it does not teach the claimed causes of the scar, or the kit. The causes of the scar do not impart patentability to the claimed method because it is expected that NSAID will have the same effect on any scar regardless to the cause. The kit is considered a composition, and the separation of the NSAID and the carrier within a kit is

within the skill of an artisan versed in the pharmaceutical art in order to increase the shelf life of the NSAID.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use the external preparation disclosed by the JP '465 to treat keloid and hypertrophic scar caused by any causes such as burn or surgical operation, motivated by the teaching of JP '465 that external preparation comprising NSAID is useful to treat skin diseases such as keloid and hypertrophic scar and does not have adverse effects, with reasonable expectation of treating any scar tissue by topical application of NSAID.

4. Claims 80, 89, 103, 109, 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,652,856 ('856) in view of US 5,552,162 ('162).

US '856 teaches method for treating fibrosis including dermal fibrosis such as keloid and hypertrophic skin caused by surgical wounds and traumatic laceration by using composition comprising the NSAID sulfasalazine in a glycol carrier (abstract; col.6, lines 15-16, 30-36; col.11, lines 66-67; col.12, lines 17-20, 27).

US '856 suggests the treatment of keloid and hypertrophic scar using NSAID, however, it does not teach the claimed amount of NSAID, or the kit. US '856 does not teach thermal insulating agent.

The claimed amount of NSAID does not impart patentability to the claims, absent evidence to the contrary. The kit is considered a composition, and the separation of the

NSAID and the carrier within a kit is within the skill of an artisan versed in the pharmaceutical art in order to increase the shelf life of the NSAID.

US '162 teaches a method for improving the size and appearance of the scar associated with keloid or hypertrophic wound healing disorder by covering the scar with thermal insulating material and active agent (abstract). The thermal insulating materials includes hydrogel and gel (col.9, lines 10-12, 27). The thermal insulating material elevates the surface temperature of the scar and consequently stimulates the collagenase activity and improves the size and the appearance of the scar (col.6, lines 1-32).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the method for improving the keloid and scar by administering a composition comprising NSAID as disclosed by US '856, and add the thermal insulating hydrogel disclosed by US '162, motivated by the teaching of US '162 that the thermal insulating material elevates the surface temperature of the scar and consequently stimulates the collagenase activity and improves the size and the appearance of the scar as desired by the applicant, with reasonable expectation of having a composition comprising the aspirin and hydrogel that improves the size and the appearance of the scar with success.

5. Claims 80 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,521,271 ('271) with the effective filing date of August 16, 1999.

US '271 teaches method of improving skin conditions such as scar by, administration of a composition that can be in the form of topical composition comprising 1-20% of hydroxyl acid such as salicylic acid and a carrier (abstract; col.3, lines 13-15, 35-37, 39-40; col.7, lines 15-23, 40; col.8, lines 19-21, 26, 30, 38-50). The hydroxyl acids are delivered topically to the skin in doses that are highly effective without causing significant skin irritation (col.3, lines 1-3).

US '271 suggests the treatment of scar by topical application of the composition comprising NSAID (col.9, lines 64-66), however, it does not teach the claimed causes of the scar, or the kit. The causes of the scar do not impart patentability to the claimed method because it is expected that NSAID will have the same effect on any scar regardless to the cause. The kit is considered a composition, and the separation of the NSAID and the carrier within a kit is within the skill of an artisan versed in the pharmaceutical art in order to increase the shelf life of the NSAID.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use the topical composition disclosed by the US '271 to treat scar caused by any causes such as burn or surgical operation, motivated by the teaching of US '271 that the topical composition comprising NSAID is delivered in a dose that is highly effective to treat scar without causing significant skin irritation, with reasonable expectation of treating any scar tissue by topical application of NSAID.

6. Claims 80, 89,103 and 109 and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '271 in view of US 5,552,162 ('162).

The teaching of US '271 are discussed above, however, US '271 does not teach the thermal insulating material.

US '162 teaches a method for improving the size and appearance of the scar associated with keloid or hypertrophic wound healing disorder by covering the scar with thermal insulating material and active agent (abstract). The thermal insulating materials includes hydrogel and gel (col.9, lines 10-12, 27). The thermal insulating material elevates the surface temperature of the scar and consequently stimulates the collagenase activity and improves the size and the appearance of the scar (col.6, lines 1-32).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the method for improving the scar by administering a composition comprising non-steroidal anti-inflammatory agent as disclosed by US '271, and add the thermal insulating hydrogel disclosed by US '162, motivated by the teaching of US '162 that the thermal insulating material elevates the surface temperature of the scar and consequently stimulates the collagenase activity and improves the size and the appearance of the scar as desired by the applicant, with reasonable expectation of having a composition comprising the aspirin and hydrogel that improves the size and the appearance of the scar with success.

7. Claims 103 and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,244,948 ('948).

Claim 103 is directed to composition, and the future intended use of the does not impart patentable weight to composition claims.

US '948 teaches topical composition comprising esters of acetylsalicylic acid in amount of 1-10%, carrier comprising water and polyethylene glycol (abstract; col.1, lines 45-50; col.2, lines 20-23, 33-35). The composition comprises gel (col.2, line 48).

US '948 does not teach the kit. The kit is a composition, and the separation of the NSAID and the carrier within a kit is within the skill of an artisan versed in the pharmaceutical art in order to increase the shelf life of the NSAID.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the composition disclosed by US '948 and deliver the composition in form of a kit comprising the carrier separate from the drug, motivated by the logic of the cosmetic art that separation of the drug and the carrier may prolong the shelf life of the drug, with reasonable expectation of having a composition comprising NSAID and carrier in form of a kit that has prolonged shelf life.

8. Claims 103 and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 27 07 537 ('537).

Claim 103 is directed to composition, and the future intended use of the does not impart patentable weight to composition claims.

DE '537 teaches formulations comprising salicylic acid in an amount of 1-3%, and carrier such as ethylene glycol. The formulation comprises gel (thermal insulating material) and a substance that relieve skin irritation.

DE '537 does not teach the kit. The kit is a composition, and the separation of the NSAID and the carrier within a kit is within the skill of an artisan versed in the pharmaceutical art in order to increase the shelf life of the NSAID.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the composition disclosed by DE '537 and deliver the composition in form of a kit comprising the carrier separate from the drug, motivated by the logic of the cosmetic art that separation of the drug and the carrier may prolong the shelf life of the drug, with reasonable expectation of having a composition comprising NSAID agent and carrier in form of a kit that has prolonged shelf life.

Response to Arguments

9. Applicant's arguments filed 10/12/2006 have been fully considered but they are not persuasive.

The main gist of applicant's argument against the obviousness rejections over JP '465, US '856, US '271 is that the references do not disclose composition consisting essentially of NDAID, and they disclose other ingredients. Applicant further argues that US '948 and DE '537 teaches scar caused by acne and not scars caused by the specific claimed conditions.

In response to these arguments, it is argued that the expression "consisting essentially of" of the claims' language limits the scope of the claim to the specified ingredients, and those that do not materially affect the basic and novel characteristics of the composition. *In re Janakirama-Rao*, 317 F 2d 951, 137 USPQ 893 (CCPA 1963).

When applicant contends that modifying components in the reference's composition are excluded by the recitation of "consisting essentially of", applicant has the burden of showing the basic and novel characteristics of the claimed composition, i.e. showing that the introduction of these components would materially change the characteristics of applicant's composition. *In re De Lajarte,* 337 F 2d 870, 143 USPQ 256 (CCPA 1964).

US '948 and DE '537 are still applicable to the claims directed to composition (103 and 11) because the future intended use does not impart patentability to the claims directed to composition. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding applicant's argument with respect to the causes of the scar, it is argued that even if acne and the claimed conditions are different diseases and have different etiology and symptoms, the process leading to the formation of the scar and the structure of the scar is assumed to be the same. Alternatively, applicant did not show that scar occurred by the claimed conditions is formed by different mechanism and it will have structure different from the scar formed by acne.

Response to Amendment

10. The declaration under 37 CFR 1.132 filed January 05, 2006, as discussed in the office action mailed 05/08/2006, is insufficient to overcome the rejection of claims 80, 89, 103, 109, and 111 based upon U.S.C. 103 (a) over US '271 and DE '537 as set forth

in the last Office action because: US '271 clearly suggested using salicylic acid to treat scars. DE '537 is currently used to reject product claims, and not method claims, and the future intended use of the product does not impart patentability to the claims.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali
Primary Examiner
Art Unit 1615

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